DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 99P-0923 /CP 1

5588 '99 JUN 29 P4:41

JUN 28 1999

Kevin Sheil
Pharmaderm – Veterinary
Division of Altana, Inc.
60 Baylis Road
Melville, New York 11747

Dear Mr. Sheil:

We refer to your suitability petition dated March 24, 1999, and filed April 2, 1999, in which you requested permission to submit an abbreviated new animal drug application (ANADA) to provide for the use of Pharmaderm's generic miconazole nitrate, which is indicated for use as an antifungal agent in dogs and cats. The proposed generic differs in strength from the pioneer product, Schering-Plough's (formerly Pittman-Moore's) Conofite® 2% Cream (NADA 95-183).

Approval of an ANADA requires a demonstration of the bioequivalence of the generic and pioneer products when administered at the same dose. The proposed generic product contains 20 mg miconazole nitrate per gram of cream, whereas the pioneer product contains 23 mg miconazole nitrate per gram of cream. The pioneer product is administered as a ¼-inch ribbon of cream once daily per square inch of lesion for 2 to 4 weeks. The proposed generic labeling directions for the amount of cream to administer would be adjusted on the generic product label to recommend topical delivery of an amount of miconazole nitrate equal to the amount delivered by the pioneer product. However, specific labeling directions that would assure a dose equal to that of the pioneer are not provided.

Change in strength is one of the allowable differences in the pioneer and generic products which may be considered in a suitability petition, as provided by the Generic Animal Drug and Patent Term Restoration Act, section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your suitability petition is approved. The Agency has determined that the change in strength (i.e., 2.0 percent miconazole base to 1.7 percent miconazole base) for the specific proposed drug product does not pose questions of safety or effectiveness. The basis for this determination is that the proposed product actually represents an intermediate strength of currently available miconazole nitrate dosage forms: approved lotion and spray (1% miconazole base), and cream (2% miconazole base). Also the uses, dose, and administration of the proposed product will conform to those of the listed drug. Thus, there are no

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investigations the Agency would require to demonstrate safety or effectiveness. Therefore, an ANADA may be submitted for the above referenced drug product.

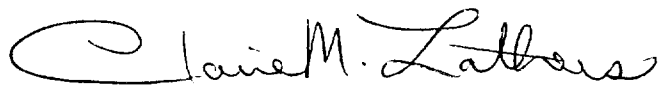
Approval of the suitability petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. The Center may at any time during the course of its review of an ANADA, request additional information necessary to evaluate the change approved under this petition.

Bioequivalence studies will be required for dogs and cats. For the purposes of the studies, you would need to show that the directions for applying the cream could be stated in such a way as to provide the same dose as the pioneer product (even though the strengths would be different). We recommend that you submit protocols for our evaluation before initiating any studies.

The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as modified dosage and other labeling changes related to the change in strength provided for under this Suitability Petition. The labeling for the proposed product will indicate clearly the difference in strength from the pioneer. We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center.

You may contact Dr. Lonnie W. Luther, Chief, Generic Animal Drugs and Quality Assurance Staff, (301) 827-0209, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,



Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

MEMO

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

5587 '99 JUN 29 P4:41

DATE: May 28, 1999

FROM: Animal Scientist
Quality Assurance Support Staff, HFV-102

SUBJECT: Suitability Petition Response for Display.

TO: Lyle Jaffe, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD
Dockets Management Branch, 301 827-6860 (V)

The attachment is the Center for Veterinary Medicine's response to Suitability Petition **SP 99P-0923CP 1**, filed as a Suitability Petition on 4/2/99. We are forwarding a copy of the signed response for public display with the petition.

A copy of the DMB cover sheet is also attached.

The Center's response to **Pharmaderm** is dated June 28, 1999.

If you have any questions, please call me at 827-0211, or FAX 594-2297.

Thank you.

Sam Hansard, Ph.D.

Attachment

Samuel Hansard, Ph.D.
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